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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,138	08/19/2004	Rango Dietrich	26230	1681

34375 7590 05/30/2007

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,138	DIETRICH ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-23 and 25-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-23 and 25-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks and amendment, filed 4/27/2007, have been received. Claims 18 – 23 and 25 – 67 are pending in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 67 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 – 23, 25 – 32, 36, 37, 58 – 67 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0018071 to Rennard in view of US 6,677,362 to Ghebre-Sellassie and US 4,042,240 to Thakker for reasons of record and those discussed below.

Applicants' arguments are responded to below.

Claims 33 – 35 and 38 – 57 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard, Ghebre-Sellaise and Thakkar as applied to claims 18 – 23,

25 – 32, 36, 37, 58 – 67 and in further view of Remmington: The Science and Practice of Pharmacy, 1995, for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

In response to applicant's argument that there is no motivation to combine the references to obtain an immediate release formulation because Rennard already teaches an immediate release formulation, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, the Ghebre-Sellassie reference clearly suggests that drugs which have poor solubility in water (such as that of instant claims) will have the advantageous property of increased bioavailability when PVP is used as a carrier.

Applicants' arguue that no details are given in the Ghebre-Sellassie reference as to the details of the advantageous effects (that is, how much the bioavailability increases), whereas Applicants' have provided a declaration, the appendix thereto providing details of how use of PVP as a carrier increases the dissolution profile of rolflumilast (the increased dissolution profile being indicative of an increased bioavailability). In response, it is noted that despite such lack of detail in the art there can be no doubt that Ghebre-Sellassie does in fact suggest the result which Applicants' claim to be the basis for non-obviousness, namely increased bioavailability (more rapid dissolution profiles), upon addition of PVP. Thus, in view of the teachings of the prior

art, it would be expected that use of PVP as a carrier for poorly water soluble drugs would increase the bioavailability and aqueous dissolution profile of said drugs. Accordingly, the results presented in the Appendix of Applicants' declaration flesh out the details of the results which could be obtained from following the teachings of the art, but they do not show any results which are not suggested by the art.

Applicants continue to argue that Thakkar does not specify what molecular weight ranges are useful, but instead merely gives a broad range of generally useful PVP molecular weights. According to Applicants', this is merely an invitation to experiment to find the useful molecular weights of PVP. In response, it is the position of the office that Thakkar's teachings of the useful molecular weight of PVP, when considered in light of the other cited references, are guidelines useful to optimize that which is taught in the other references. Since Ghebre-Sellassie teaches an advantageous result obtainable by use of PVP as a carrier without specifying the molecular weight of PVP needed to obtain that result, the artisan would look to references like Thakkar, which shows what molecular weights of PVP are useful as carriers for drugs. Using the information in Thakkar, which shows a very limited molecular weight range of PVP to be useful. (It is noted that while Thakkar teaches PVP with an average molecular weight from 10,000 – 360,000 daltons, the artisan would recognize that PVP may have an average molecular weight as low as a few hundred Daltons or as high as five million Daltons. Bearing this in mind, the molecular weight range taught by Thakkar is actually fairly narrow.) It is generally obvious to optimize a results-effective variable. In this case, the artisan would be able to do so

without any undue experimentation and with a reasonable expectation of success because Thakkar teaches the narrow range of PVP molecular weights that are useful to the artisan.

Applicants' have also submitted a declaration, which has been fully considered. The declaration is essentially an opinion declaration, which alleges what the prior art teaches and does not teach and then proceeds to draw legal conclusions from this discussion. This is not persuasive, because there is no factual basis for the legal conclusions drawn in the declaration. The declaration also presents data showing that the dissolution profile of rolflumilast is more rapid when PVP is used as a carrier. This result is not unexpected, however, since it merely reaches the same conclusion that Ghebre-Sellassie reached before the time of the invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

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